



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

New England District

93348d

One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 596-7700  
FAX: (781) 596-7896

**WARNING LETTER**

**NWE-18-02W**

**June 10, 2002**

**VIA FEDEX**

Joel G. Newman, President and CEO  
United Co-op Farmers, Inc.  
22 Kimball Place  
Fitchburg, Massachusetts 01420

Dear Mr. Newman:

An inspection of your medicated feed mill located in Fitchburg, Massachusetts, conducted by Food and Drug Investigator Troy Petrillo on April 22-25, and May 13, 2002, found a significant deviation from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 225). This deviation causes medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviation is as follows:

- For feeds requiring an approved license for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year. If the medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested (21 CFR 225.58(b)(1)). Although such feeds were produced at the Fitchburg mill of United Co-op Farmers, Inc, no assays were performed in the years 2001 and 2002.

The above is not intended to be an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with all aspects of the law.

You should take prompt action to correct this CGMP violation, and you should establish procedures whereby such violations do not recur. Failure to promptly correct this CGMP violation may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License under section 512(m)(4)(B)(ii) of the Act and 21 CFR 515.22(c)(2). (This letter constitutes official notification under the law.) Based on the results of the April 22-25, and May 13, 2001 inspection, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the medicated feeds at the United Co-op Farmers mill at Fitchburg, Massachusetts are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office, in writing, within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the noted CGMP violation and prevent its recurrence. If corrective action cannot be completed fifteen (15) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made. FDA has received and will consider the response memorandum faxed to FDA on behalf of United Co-op Farmers by Stanley Moreau on April 25, 2002, and the fax from Mr. Moreau to FDA dated April 30, 2002. FDA will evaluate the corrections described in that memorandum and that fax during the next FDA inspection of your Fitchburg facility.

Your response to this letter should be directed to Bruce R. Ota, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, Fourth Floor, Stoneham, Massachusetts 02180.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gail T. Costello', with a large, stylized flourish extending to the right.

Gail T. Costello  
District Director  
New England District